

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

THIS PAGE BLANK (USPTO)

(12) UK Patent Application (19) GB (11) 2 275 420 (13) A

(43) Date of A Publication 31.08.1994

(21) Application No 9303504.6

(22) Date of Filing 22.02.1993

(71) Applicant(s)

David Ramon Gaunt
20 The Reddings, Red Road, BOREHAMWOOD,
Hertfordshire, WD6 4SS, United Kingdom

Scott Glickman
Royal National Orthopaedic Hospital, Brockley Hill,
Stanmore, Middlesex, HA7 4LP, United Kingdom

(72) Inventor(s)

David Ramon Gaunt
Scott Glickman

(74) Agent and/or Address for Service

Hyde, Heide & O'Donnell
10-12 Priests Bridge, LONDON, SW15 5JE,
United Kingdom

(51) INT CL⁵

A61M 39/02 , A61B 17/34 , A61M 25/01

(52) UK CL (Edition M)

A5R RAM REC RGB

(56) Documents Cited

WO 90/07311 A1 US 5082005 A

(58) Field of Search

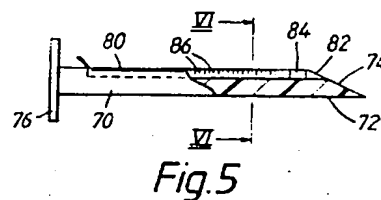
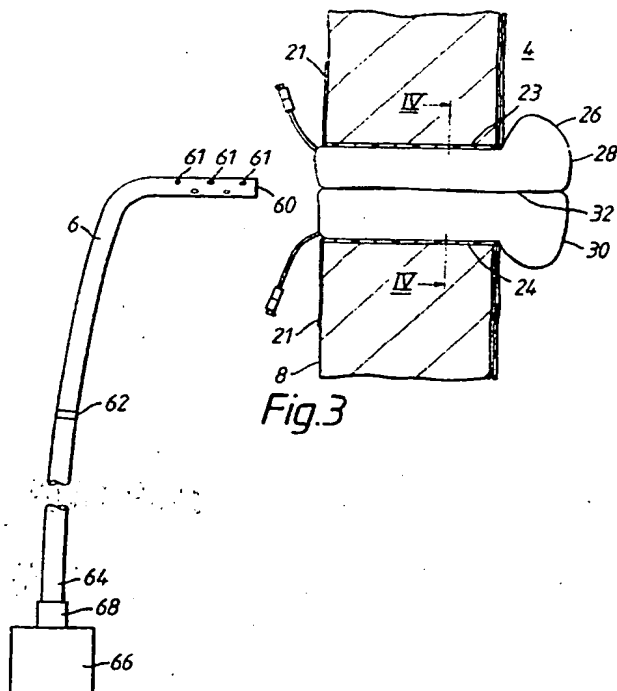
UK CL (Edition M) A5R RAM RAP RCE RGB RGD
INT CL⁵ A61F 2/00 , A61M 25/00 25/04 39/00 39/02
39/04
ONLINE DATABASES: WPI, MEDENG

(54) Organ access system and trocar assembly

(57) A medico-surgical system for access to a hollow viscus 4 includes a member (2, Fig. 1) adapted to extend through an opening in the skin into the viscus of the patient so that one end of the member is located within the viscus and the other end terminates adjacent the skin. Balloons 28 and 30 are provided for retaining the one end of the member within the viscus. The balloons 28 and 30 also act as sealing means, adapted to seal the opening whilst allowing intermittent access to the viscus 4, e.g. by means of a catheter 6.

Alternatively, the system comprises a tubular sleeve (92, Fig. 10), an inflatable cuff (94, Fig. 10) and a diaphragm (96, Fig. 10) having a self-sealing aperture.

A trocar assembly 70 has an inclined cutting surface 74 and a channel (78, Fig. 6) into which is slid a catheter 86.

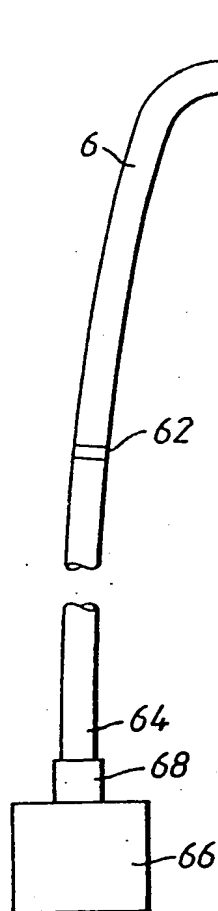
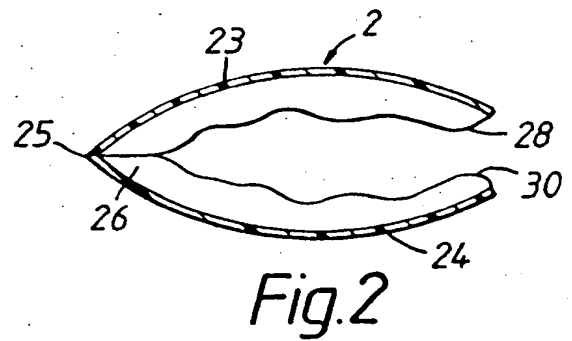
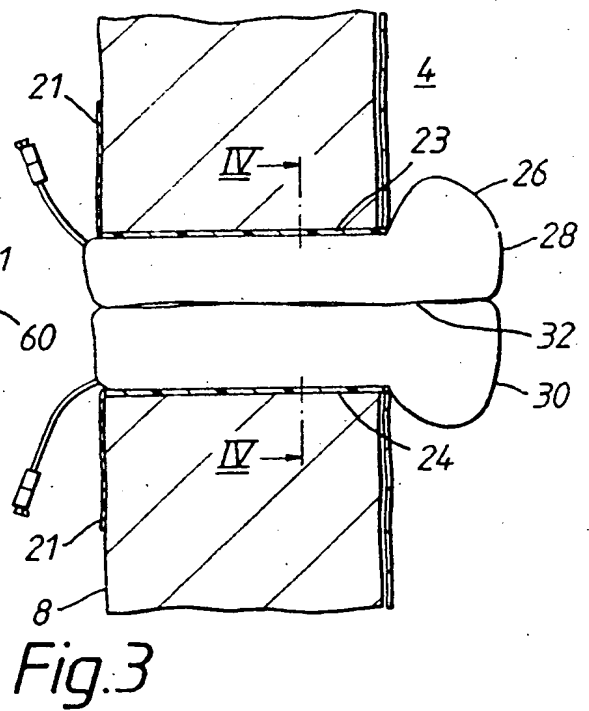
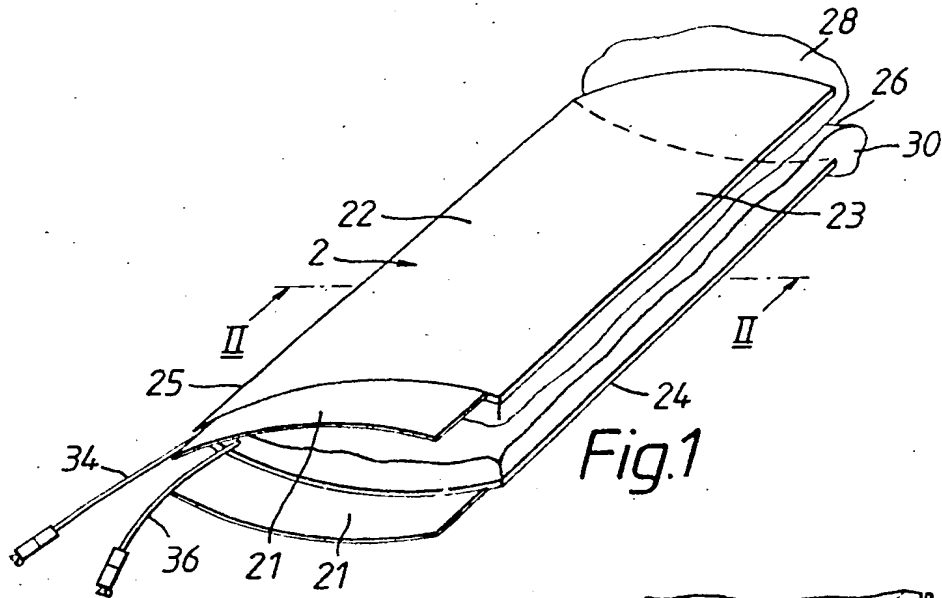


GB 2 275 420 A

At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date within the period prescribed by Rule 25(1) of the Patents Rules 1990.

1/3



2/3

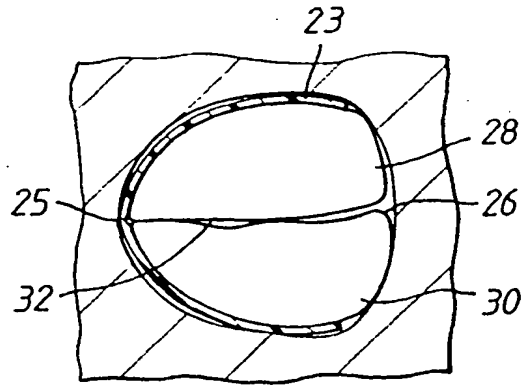


Fig. 4

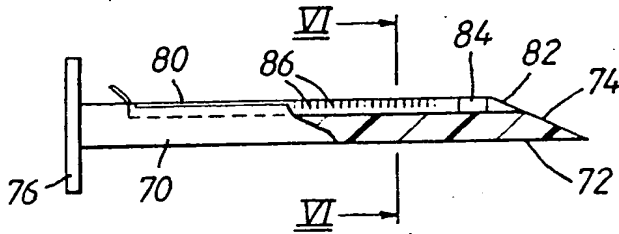


Fig. 5

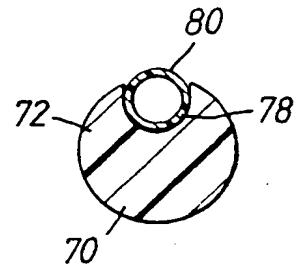


Fig. 6

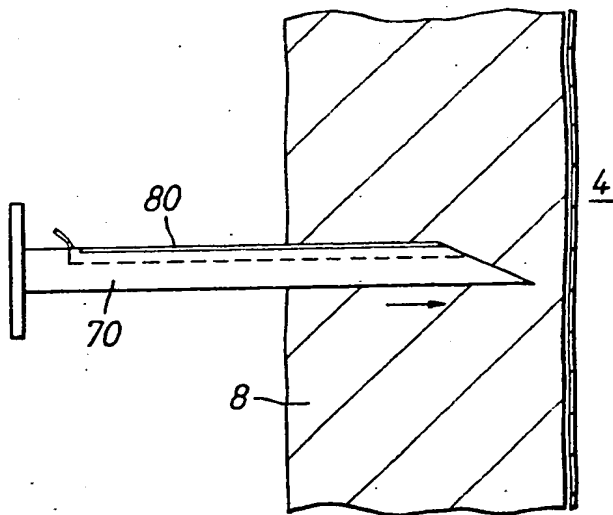


Fig. 7

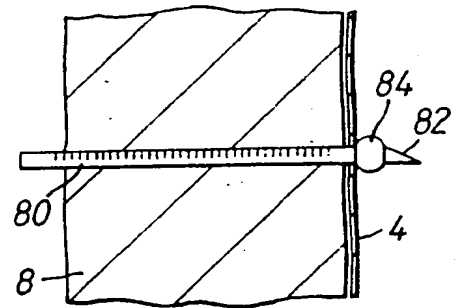


Fig. 8

3/3

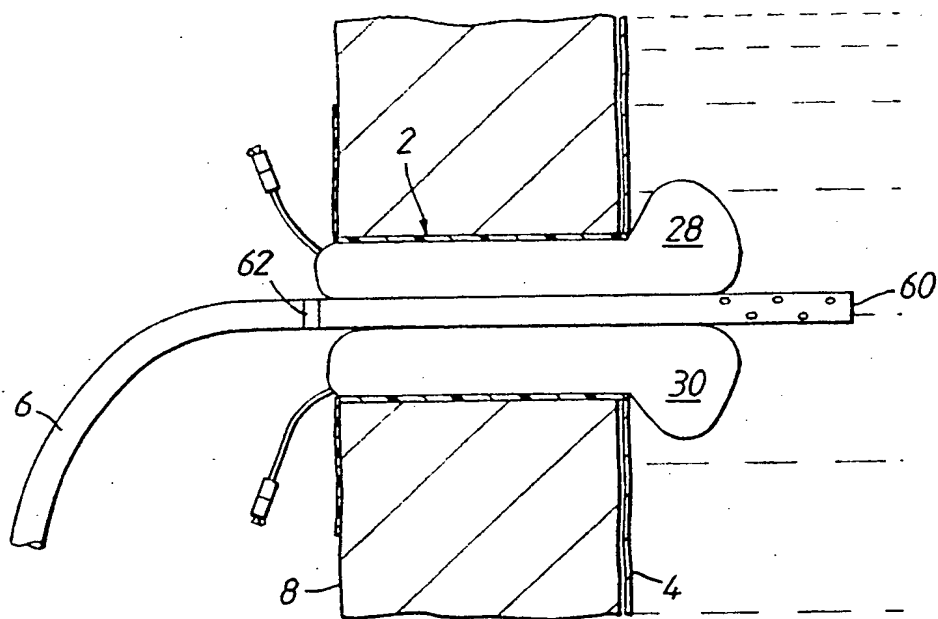


Fig.9

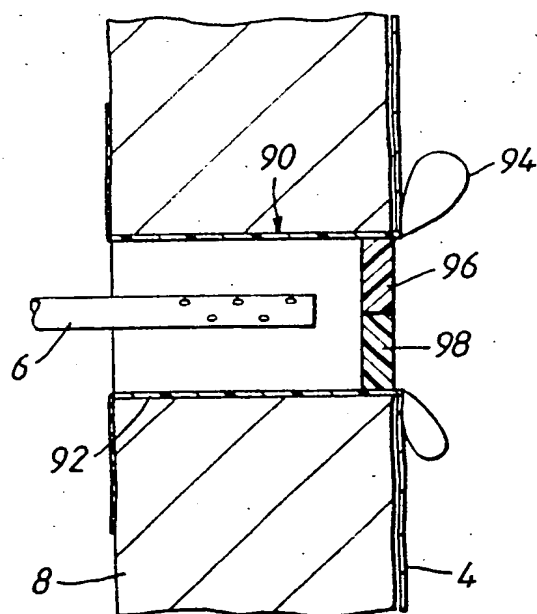


Fig.10

ORGAN ACCESS SYSTEMS AND TROCAR ASSEMBLIES

This invention relates to organ access systems and trocar assemblies.

The invention is more particularly, but not exclusively, concerned with bladder management systems.

In some clinical conditions, such as when nerve supply to the bladder is damaged, for example, after spinal trauma, it is necessary to drain the bladder artificially. Artificial drainage may also be necessary following surgery or when the genito-urinary system is blocked. This can be done by means of a catheter or the like inserted via the urethra. The disadvantage of this is that it can cause irritation, discomfort and infection. It can also lead to the formation of calculus and trauma causing strictures and false passages. Urethral incompetence can be a problem with women.

The catheter can be left in place to allow urine to drain continuously out of the bladder into a urine leg bag or the like. Alternatively, the catheter can be inserted intermittently to allow periodic emptying of the bladder. This has the advantages of reducing infection and of allowing the bladder to fill and empty in a way that more closely mimics normal physiology. It also

avoids the need to wear a drainage bag. There are, however, problems in repeatedly inserting a catheter into the urethra in that there is a repeated urethral trauma. Where the patient performs self catheterization, this can require manual dexterity and is often difficult and offensive to the patient. In cases where the patient retains urethral sensation, appreciable discomfort can be caused. There is also the risk of forcing urethral organisms into the bladder with each catheterization.

An alternative technique involves suprapubic catheterization in which a catheter extends into the bladder through a surgically-made opening in the abdominal wall. One end of the catheter is anchored in the bladder such as by means of an inflatable balloon or by coiling the end of the catheter. The other end of the catheter extends to a urine leg bag or similar receptacle so that urine can continuously drain away from the bladder. This suprapubic technique avoids trauma to the urethra but is still prone to infection and the accumulation of calculus. The technique also suffers from an additional problem in that it can be difficult to maintain the track into the bladder when the catheter is changed or if it should fall out. The risk that the track into the bladder may be lost means that replacement of the catheter is usually carried out in hospital rather than by nurses, patients or by their carers working in the community.

Examples of suprapubic catheter systems are described in US 3,640,281, US 3,924,633, US 3,860,006 and US 4,419,094.

There are other situations where access is required to a hollow organ or viscus such as where it is desired to supply fluid to the organ or where it is necessary to insert an endoscope.

It is one object of the present invention to provide an improved system for access to a hollow viscus.

According to one aspect of the present invention there is provided a medico-surgical system for access to a hollow viscus including a member adapted to extend through an opening in the skin into the hollow viscus of the patient so that one end of the member is located within the hollow viscus and the other end of the member terminates adjacent the skin, means for retaining the one end of the member within the hollow viscus, and sealing means adapted to seal the member whilst allowing intermittent access to the hollow viscus.

The system may be a bladder management system in which the one end of the member is located within the bladder and the other end of the member terminates adjacent the skin of the abdominal wall.

In this way, the bladder can be drained intermittently without the need for urethral catheterization. Furthermore, urine does not lie in the member, thereby reducing the build up of calculus. The sealing means also reduces the risk of infection.

The member may take the form of two leaves hinged together about a longitudinal edge and with their opposite longitudinal edge free.

The sealing means is preferably adapted to be opened by insertion of means within the member. The means insertable within the member is preferably a catheter through which urine flows out of the bladder. The sealing means may include a balloon member that normally effects the seal. Preferably, the seal is effected along substantially the entire length of the member. The means for retaining the member in the hollow viscus preferably also includes a balloon member.

It is another object of the present invention to provide an improved trocar assembly for use in making access to a hollow viscus.

According to the other aspect of the present invention there is provided a trocar assembly comprising a substantially rigid elongate trocar member having one end provided with an inclined, cutting surface adapted to penetrate body tissue, a channel extending along a major part at least of the length of the trocar member and opening at the one end of the trocar member, and a catheter removably located within the channel such that after penetration of a hollow viscus by the one end of the trocar, the catheter may be slid forwardly along the channel as the trocar is withdrawn to leave the catheter in position with one end in the hollow viscus.

Preferably, the channel opens along its length on a surface of the trocar. The catheter preferably has a locating cuff encircling it close to its one end by which the catheter can be retained in the hollow viscus.

Two bladder management systems according to the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a perspective side elevation view of a bladder management system deflated, prior to use;

Figure 2 is a transverse section along the line II - II of Figure 1;

Figure 3 is a side elevation view of the bladder management system inflated during use;

Figure 4 is a transverse section along the line IV - IV of Figure 3;

Figure 5 is a partly cut-away side elevation view of a trocar used to install the bladder management system;

Figure 6 is a transverse section of the trocar along the line VI - VI of Figure 5, to an enlarged scale;

Figures 7 and 8 illustrate steps prior to insertion of the bladder management system;

Figure 9 is a sectional side elevation view of the bladder management system during drainage; and

Figure 10 is a sectional side elevation view of an alternative system.

With reference to Figures 1 to 4, the bladder management system comprises two parts namely, a sealing member or accessor 2 which extends into the bladder 4, and a catheter 6 by which the accessor can be opened to allow drainage of urine from the bladder.

The accessor 2 comprises an outer shell or member 22 formed by two elongate leaves 23 and 24 of a bendable plastics material which each are bowed across their width with their concave surfaces facing one another. The leaves 23 and 24 are hinged together along one edge 25, their opposite edges being free. In this respect, the leaves may be an integral one-piece construction with the hinge being formed by a region of reduced thickness. Typically, the shell 22 is about 50mm long with each leaf 23 and 24 being about 20mm wide. The length of the accessor 2 is such that it extends outwardly from the bladder 4 as far as the external, skin surface of the anterior abdominal wall 8 where it terminates. At their external ends, each leaf 23 and 24 has an annular flange 21, or tabs or the like, which are secured to the skin surface such as by means of an adhesive, for example, a karaya stoma wafer. The accessor 2 also includes a balloon assembly 26 within the shell 22 which comprises two elongate balloons 28 and 30 of oval section, or may be formed by a single balloon of U-shape. The use of two balloons is, however, preferred for safety reasons, each

balloon by itself being sufficient to retain the accessor in the bladder and preserve the track. The balloons 28 and 30 are of a thin, flexible plastics material being about 60mm long, that is, longer than the shell 22. At its, external, left-hand end, each balloon 28 and 30 terminates level with, and is attached to, the external end of a respective leaf 23 or 24. At its internal, right-hand end, each balloon 28 and 30 is attached to the internal end of a respective leaf 23 and 24 and projects from it. Along their length, on one side, the balloons 28 and 30 are joined together and to the hinged edge 25 of the two leaves 23 and 24. On the opposite side, the balloons 28 and 30 are joined to the free, longitudinal edge of a respective one of the leaves 23 and 24. When uninflated, as shown in Figures 1 and 2, the two leaves 23 and 24 lie relatively close together with most of the balloon assembly 26 enclosed between the leaves except for that part which protudes from the right-hand end. When inflated, as shown in Figures 3 and 4, the balloons 28 and 30 open apart the two leaves 23 and 24 into a part circular configuration. Inflation of the balloons 28 and 30 beyond the longitudinal edge of the leaves 23 and 24 is limited by contact of the balloons with the surrounding tissue, so that the overall section of the accessor 2 when installed is generally circular.

The internal end of the balloon assembly 26 bulges outwardly into the bladder 4 thereby retaining the accessor 2 in position.

Alternative means for retaining the internal end of the accessor in the bladder could be used. When inflated, the two balloons 28 and 30 contact each other along their entire length within the shell, thereby sealing the passage 32 into the bladder 4. An inflation line 34 and 36 extends from each balloon 28 and 30 for use in inflation and deflation. The inflation lines 34 and 36 may be provided with a valve and a cap for sealing the lines. The material forming the balloons 28 and 30 may itself be resilient so that it is stretched on inflation by a relatively high internal pressure; alternatively, the balloons may be of the low-pressure kind, being inflated, but not stretched, by the air within them. In a further alternative embodiment, the balloons could be filled with a resilient foam. Insertion and withdrawal would then be carried out by applying negative pressure to suck the wall of the balloons about their foam filling, thereby reducing their cross section.

The catheter 6, forming the second part of the system, is typically about 600mm long and has an external diameter of about 5mm. The catheter 6 is made of a bendable plastics material such as PVC. One end 60 of the catheter is open and has several aperture 61 in its wall spread over a distance of about 30mm from the open end. At about 90mm from the open end, the catheter is provided with a marker 62 or a stop such as a flange, to indicate the extent of insertion. Conventional catheters could be used for drainage. At its opposite end 64, the catheter is coupled to a conventional urine bottle 66 or other urine receptacle, such as by means of a coupling 68. Alternatively, the end 64 could be open and simply held over a w.c. pan or urinal when discharge of urine is desired.

The bladder management system may be installed by means of an introducer or trocar assembly 70 shown in Figures 5 and 6. The assembly 70 comprises a trocar 72 of a rigid perspex, or other material, which is of cylindrical shape and circular section having a bevelled cutting point 74 at one end and a handle 76 at its opposite end. Typically, the trocar is 200mm long and 15mm in diameter. Along one edge, the trocar has a channel 78 of part circular section which opens along the length of the trocar. Slid into the channel 78 is a catheter 80 of a rigid perspex, or other material, which

is about 150mm long and has a diameter of about 4mm. The opening of the channel 78 is narrower than its diameter so that the catheter 80 is retained in the trocar 72. The forward end of the catheter 80 has a bevelled tip 82 which aligns with the bevelled tip 74 of the trocar. An inflatable cuff 84 encircles the catheter close to its bevelled tip 82.

In use, with a full bladder, the tip 74 of the introducer assembly 70 is pushed through the skin and tissue 8 of the abdomen, as shown in Figure 7, and into the bladder 4. The extent of penetration can be monitored by observation of graduated markings 86 on the catheter. Penetration of the bladder 4 is readily apparent by the flow of urine out of the catheter. The trocar 72 is then pulled rearwardly out of the patient, leaving the catheter 80 in place. The cuff 84 on the catheter 80 is inflated as the trocar is removed so as to secure the catheter in the bladder 4, as shown in Figure 8. A sterile urine specimen can be collected during initial drainage of the bladder 4 through the catheter 80. The purpose of the catheter 80 is to maintain the initial track into the bladder and drain the bladder prior to insertion of the accessor. It also enables the length of the track between the bladder 4 and the skin 8 of the abdomen to be measured.

The accessor 2 is then inserted in its deflated state by opening the shell 22 slightly so that the catheter 80 can be placed between two leaves 23 and 24. The leaves are held together as the accessor 2 is slid along the outside of the catheter 80 until its patient end is located in the bladder 4. It will be appreciated that the size of opening made by the trocar assembly 70 is greater than the diameter of the catheter 80 so that there is room to accommodate the larger size of the accessor. The bowed shape of the leaves 23 and 24 increase its rigidity in the longitudinal direction enabling it to be slid without buckling against friction with the tissue. The accessor 2 is then inflated so that the balloons 28 and 30 secure it in the bladder 4 and seal with the outside of the catheter 80, confining any residual flow of urine to the catheter. The catheter 80 can then be removed by deflating its cuff 84 and pulling it out between the balloons 28 and 30 which seal together behind it. Alternatively, an expansible dilator or a series of increasingly larger dilators could be slid alongside the catheter 80 and the track dilated to allow subsequent insertion of the accessor.

Once in position, with the balloons 28 and 30 inflated, the accessor 2 prevents flow of urine out of the bladder 4. When it is desired to empty the bladder, the catheter 6 is pushed into the accessor 2 along the passage 32 between the two balloons 28 and 30 until the marker 62 lies level with the external end of the accessor, or until urine starts to flow through the catheter within the accessor as shown in Figure 9. The balloons 28 and 30 in the accessor 2 seal with the outside of the catheter 6 and prevent urine seeping between the catheter and the accessor.

It can be seen that the bladder management system has several advantages. Firstly, because the bladder is drained intermittently rather than continuously, the user does not need to wear a leg bag. Secondly, the user can drain urine himself, as and when he wishes, without the need for assistance. There is no need for urethral catheterization, thereby avoiding the discomfort, trauma and the attendant risk of ascending infection. Furthermore, there is no risk of blockage caused by the build-up of calculus, because the catheter along which the urine is discharged is clean before each insertion through the accessor.

A very important advantage of the accessor is that replacement is relatively easy and presents no significant risk of the loss of track as compared with previous suprapubic catheters. Replacement is carried out by deflating slightly the balloon assembly of the original accessor whilst retaining sufficient air in the right-hand end of the balloons to provide continued retention. The replacement accessor, in a deflated condition, is pushed between the two leaves of the original accessor until its external end is level with that of the original accessor. The replacement accessor is now inflated and the original accessor deflated. The original accessor is then pulled out of the body along the outside of the replacement accessor.

The accessor is not confined to use with bladder management but could be used in any application where access is required to a hollow viscus or organ. For example, it could be used to provide a site for intermittent administration of fluid or medicament to a viscus via a tube inserted through the accessor. Alternatively, it could be used to enable access of an endoscope or a surgical instrument.

The trocar assembly also has applications other than in making access to a bladder.

It will be appreciated that the accessor could take various different forms. For example, the accessor could be of tubular form with two internal, D-shape balloons. Such a configuration would, however, be more difficult to replace than the accessor described above. In another example, shown in Figure 10, the accessor 90 has a tubular sleeve 92, that provides the track between the bladder 4 and the skin wall 8, and an inflatable cuff 94 which locates the accessor within the bladder. Instead of sealing the accessor by means of inflated balloons, a resilient diaphragm 96 is located close to the internal end of the accessor which has a self-sealing central aperture 98. When the catheter 6 is inserted, it extends through the aperture 98, the diaphragm 96 forming a wiping seal with the outside of the catheter. When the catheter is withdrawn, the aperture 98 resumes its sealed, closed state. Again, this accessor would be more difficult to replace, it would also retain more urine within it than the balloon accessor.

Although it is preferable that urine flows along a catheter inserted in the accessor, it could flow through the accessor itself, if the seal were opened by some means such as a rod or by partial deflation of the balloons. In this case, the accessor would need to be coupled at the skin surface to a receptacle. This alternative technique is probably only of practical use in emergency situations.

CLAIMS

1. A medico-surgical system for access to a hollow viscus including a member adapted to extend through an opening in the skin into the hollow viscus of the patient so that one end of the member is located within the hollow viscus and the other end of the member terminates adjacent the skin, means for retaining the one end of the member within the hollow viscus, and sealing means adapted to seal the member whilst allowing intermittent access to the hollow viscus.
2. A medico-surgical system according to claim 1, which is a bladder management system in which one end of the member is located within the bladder and the other end of the member terminates adjacent the skin of the abdominal wall.
3. A medico-surgical system according to claim 1 or 2, wherein the member takes the form of two leaves hinged together about a longitudinal edge with their opposite longitudinal edge free.
4. A medico-surgical system according to any preceding claim, wherein the sealing means is adapted to be opened by insertion of means within the member.
5. A medico-surgical system according to claim 4, wherein the means insertable within the member is a catheter.
6. A medico-surgical system according to any preceding claim, wherein the sealing means includes a balloon member.
7. A medico-surgical system according to any preceding claim, wherein the seal is effected along substantially the entire length of the member.

8. A medico-surgical system according to any preceding claim, wherein the means for retaining the member in the hollow viscus includes a balloon member.

9. A trocar assembly comprising a substantially rigid elongate trocar member having one end provided with an inclined cutting surface, adapted to penetrate body tissue, a channel extending along a major part at least of the length of the trocar member and opening at one end of the trocar member, and a catheter removably located within the channel such that after penetration of a hollow viscus by one end of the trocar, the catheter may be slid forward along the channel as the trocar is withdrawn to leave the catheter in position with one end in the hollow viscus.

10. A trocar assembly according to claim 9, wherein the channel opens along its length on a surface of the trocar.

11. A trocar assembly according to claim 9 or 10, wherein the catheter has a locating cuff encircling it close to its one end by which the catheter can be retained in the hollow viscus.

12. An organ access system substantially as herein described with reference to the accompanying drawings.

13. A trocar assembly substantially as herein described with reference to the accompanying drawings.

<p>Relevant Technical Fields</p>	<p>Search Examiner MISS M M KELMAN</p>
<p>(i) UK Cl (Ed.M) A5R (RAM, RAP, RCE, RGB, RGD) (ii) Int Cl (Ed.5) A61F 2/00; A61M 25/00, 25/04, 39/00, 39/02, 39/04</p>	<p>Date of completion of Search 25 APRIL 1994</p>
<p>Databases (see below) (i) UK Patent Office collections of GB, EP, WO and US patent specifications. (ii) ONLINE DATABASES: WPI, MEDENG</p>	<p>Documents considered relevant following a search in respect of Claims :- 1 to 8 and 12</p>

Categories of documents

<p>X: Document indicating lack of novelty or of inventive step.</p>	<p>P: Document published on or after the declared priority date but before the filing date of the present application.</p>
<p>Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.</p>	<p>E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.</p>
<p>A: Document indicating technological background and/or state of the art.</p>	<p>&: Member of the same patent family; corresponding document.</p>

Category	Identity of document and relevant passages	Relevant to claim(s)
X	WO 90/07311 A1 (BUKH MEDITEC) see the Figures	1
X	US 5082005 A (KALDANY) see the Figures	1,4,5,7

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).